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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,615	10/10/2001	Lisa A. Vala	5511USA	8746

30173 7590 09/19/2002

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EXAMINER

WILLIS, MICHAEL A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,615

Applicant(s)

VALA ET AL.

Examiner

Michael A. Willis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5. 6) ☐ Other: _____

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DETAILED ACTION

Information Disclosure Statement

Applicant's Information Disclosure Statements of 13 December 2001 and 2 May 2002 are entered. A signed copy is attached.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 2, 17, and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by See (US Pat. 5,747,464). See discloses a combination of beta-sitosterol and pectin (see abstract). Example 1 is a mixture of 30 mg of pectin with beta-sitosterol in a 727 mg tablet (see col. 2, line 60 through col. 3, line 15). The invention is related to a method for the reduction of serum cholesterol (see col. 1, lines 10-12).

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Claims 1-3, 11-18, and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tiainen et al (WO 98/13023). Tiainen discloses the use of sterols in edible products as cholesterol-lowering agents (see page 8, lines 21-29; see also claims 46-47). The sterols include beta-sitosterol and other sterols (see page 4, line 31 through page 5, line 4). The amount of sterol ranges from 0.5-10%, and a jellying agent is present in amounts from 0-5% (see page 10, lines 23-32). A preferred jellying agent is pectin (see page 11, lines 1-2). Tiainen further discloses that the cholesterol-lowering effect can be increased by using pectin in the products (see page 11, lines 12-21). A number of products are described, including dairy based products, yogurt, and cream (see page 12, lines 10-16). The products described meet the limitation of a bakery product or snack product.

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Bell et al (US Pat. 6,365,176). Bell discloses a nutritional supplement comprising from 1-25 grams carbohydrate and from 0.5-4 grams sterol (see col. 2, lines 3-20; see also claim 25). The carbohydrate can be barley or psyllium (see col. 2, lines 10-11; and col. 5, line 19 through col. 6, line 23). The sterol can be beta-sitosterol, campesterol, or stigmasterol (see col. 8, lines 35-67). A variety of forms are disclosed including confections, ice cream, snack bars, and beverages (see col. 2, lines 21-37). Additional components include yogurt (see col. 11, lines 50-55). The limitations of claims 4-11 and 13-16, when understood in their

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broadest reasonable interpretation, are met by the products described by Bell (see col. 2, lines 21-37; col. 11, lines 35-55; col. 12, lines 6-46; and claims 1-6).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on alt. Mondays and Tuesday to Friday (9am-6:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis
Examiner
Art Unit 1617

maw
September 17, 2002



SREENI PADMANABHAN
PRIMARY EXAMINER

9/18/02